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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/707,655	11/07/00	HIRSCH	A	INS-31061-A

022202 HM12/1024
WHYTE HIRSCHBOECK DUDEK S C
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EXAMINER	
TATE,C	
ART UNIT	**PAPER NUMBER**
1651	7

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/707,655	Hirsch
Examiner	**Art Unit**
Christopher Tate	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 20, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *24-48* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *24-48* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2 & 6*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Applicant's election of the odorant species being a mixture of licorice-based and odorant and a cucumber odorant in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an article of manufacturer having the unusual disclosed/claimed functional effect (increasing and/or decreasing blood flow to the vagina) comprising the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) and/or mixtures thereof instantly demonstrated, does not reasonably provide enablement for an article of manufacturer having the unusual disclosed functional effect comprising any undefined odorant therein and/or the subjective odorants instantly claimed (see, e.g., claims 34, 35, 37, 39, 40, 43, 44, 47, and 48 - see USC 112, 2nd paragr. below with respect to these claims). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Based upon Applicant's response and Declaration of July 6, 2001 in copending parent Application No. 09/211,507, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) act to alter blood flow to the vagina via inhaling an effective amount thereof. However, the claims encompass an article of manufacturer designed for such unusual use comprising any undefined odorant therein and/or the subjective odorants instantly claimed (see, e.g., claims 34, 35, 37, 39, 40, 43, 44, 47, and 48) which is clearly beyond the scope of the instantly disclosed invention. The instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled - e.g., based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty™ has a distinct odor from that of some other licorice based products such as anise), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked barbecue sauce containing various spices, or something else?). In addition, it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause a

decrease in blood flow to the vagina in other females. Further, as disclosed by Doty (Philadelphia Sensorics, 1983), there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell (see, e.g., pages 16-18). Therefore, altering blood flow to the vagina via the inhalation of such odorants, including the undefined and/or broadly defined odorants instantly claimed, as well as any undefined amounts thereof, is considered to be highly unpredictable between females based upon such variables.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and use an article of manufacture having the unusual disclosed/claimed functional effect, other than using one of the particular demonstrated commercial odorants or mixtures thereof, in an amount effective to provide the claimed alteration in blood flow to the vagina.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 34, 35, 37, 39, 40, 43, 44, 47, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 is rendered vague and indefinite by the phrase "wherein the concentration of the odorant is at about 25-55 decismel units" because it is unclear as to what this concentration level relates to - e.g., is this the level of decismel units within each unit dosage or just a level of odorant in some initial odorant preparation from which such dosage units are prepared from?

Claim 32 is rendered vague and indefinite by the phrase "wherein the dispenser has a tip impregnated with the odorant". It is unclear as to what is actually being defined by "tip" since essentially every dispenser has some type of tip (tip means "end of an object"). Is this defining a cap, nozzle, or some other device which is attached to the dispenser, or something else?.

The metes and bounds of the subjective odorants recited in claims 34, 35, 37, 39, 40, 43, 44, 47, and 48 are not clearly nor adequately delineated making the claims unclear. For example, based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty™ has a distinct odor from that of some other licorice based products such as anise or other products having licorice as a base in combination with other ingredients), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked

barbecue sauce containing various spices, or something else?). The subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients within the claimed article of manufacture) causes these claims to be very ambiguous and unclear.

Please note for the art rejections below, the elected species is free of the art (i.e., a mixture of cucumber- and licorice-based odorants). Therefore, another odorant from those recited: a cherry odorant, was selected by the examiner. Thus, the claims have been examined over the art only insofar as they read on a cherry odorant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 26-29, 31, 32, 36, 39, 41, 42, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunze (US 5,575,992), by Hyman (US 4,285,468), or by Doty (Philadelphia Sensorics, 1983) with evidence provided by Sweeny et al. (US 4,493,869).

Kunze teaches an article of manufacture (a fragrance cartridge in a vessel/container with a lid/cap) comprising an odorant such as cherry odorant produced by Aromatech of Somerville, NJ or by Hogan Fragrances of New York, NY or by Carrubba, Inc. of Milford, CN (see, e.g., paragraph bridging cols 2-3).

Hyman teaches an article of manufacturer (a blister pack-type article) comprising a volatile substance (odorant) such as cherry therein (see, e.g., col 5, lines 26-35).

Doty et al. teach an article of manufacture known as Microfragrance samples™ (which is a registered trademark of the 3M Corporation, St. Paul, Minnesota) comprising microencapsulated odorants including cherry odorant therein (see, e.g., pages 3-5, Experiment 1, pages 6-7 including Figure 2). As evidenced by Sweeny et al. (an inventor with the 3M Corporation), the Microfragrance samples disclosed by Doty et al. are contained within a manufactured article whereby the odorant is released by rupturing the microcapsules therein - e.g., a scratch and sniff type odor patch article (see, e.g., col 1, lines 62-68, and col 3, lines 6-10).

Please note that the concentration and/or decismel units (which appears to be a unit of measure seldom used in the odorant art other than by applicant) instantly claimed fails to define what they relate to with respect to the claimed unit dosage and, as such, the fragrance cartridge of Kunze, the blister pack-type product of Hyman, and the Microfragrance samples of Doty are (at the least) deemed to contain such a level at some point (e.g., within the initial fragrance prior to incorporating into the fragrance cartridge, blister pack, and/or Microfragrance samples, within each of the cartridge/blister pack/samples themselves, and/or within multiple cartridges/blister packs/samples). Further, since there are no recited conditions with respect to administering the odorant so as to effect an increase and/or decrease of blood flow to the vagina by the claimed percentage ranges, the inhalation thereof would inherently bring about such an effect (e.g., at some point - perhaps after inhaling for minutes or hours) at least in some female individuals,

especially given the extreme variability of the blood flow effects on different females caused thereby, as instantly disclosed. Further, the fragrance cartridge and Microfragrance sample substrates disclosed by the cited references would inherently be impregnated at a tip (i.e., at an end).

Please note that it is legally well established that printed matter - e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, *per se* - i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., *In re Haller*, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claims 24, 26-29, 31, 36, 39, 41, 42, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Vlahakis et al. (US 5,419,879).

Vlahakis et al. teach an article of manufacture comprising an odorant such as a cherry odorant therein which is contained in a vessel having a lid/cap (outer plastic covering housing the odorant) - see, e.g., Figs 2-3, col 8, lines 32-40, claims 17, 18, and 25. Again, please note that the concentration and/or decismel units (which appears to be a unit of measure seldom used in the odorant art other than by applicant) instantly claimed fails to define what they relate to with respect to the claimed unit dosage and, as such, the cherry odorant article disclosed by Vlahakis et al. is (at the least) deemed to contain such a level at some point (e.g., within the initial fragrance

prior to incorporating into the gel composition therein, or within a certain quantity of the gel composition). Further, since there are no recited conditions with respect to administering the odorant so as to effect an increase and/or decrease of blood flow to the vagina by the claimed percentage ranges, the inhalation thereof would inherently bring about such an effect (e.g., at some point - perhaps after inhaling for minutes or hours) at least in some female individuals, especially given the extreme variability of the blood flow effects on different females caused thereby, as instantly disclosed.

Also, again please note that it is legally well established that printed matter - e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, *per se* - i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., *In re Haller*, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24, 26-31, 36, 39, 41, 42, and 45-48 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nicolicchia (US 5,770,206).

Nicolicchia teaches an article of manufacture, an erotic body oil, which comprises cherry fragrance/odorant, whereby the final product is bottled. Although not expressly taught, such a bottled product (vessel) would inherently have a lid. However, in the alternative, it would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to place a lid on the bottled product of Nicolicchia to effectively contain the liquid oil therein as is conventionally performed in the art.

Again, please note that the concentration and/or decismel units (which appears to be a unit of measure seldom used in the odorant art other than by applicant) instantly claimed fails to define what they relate to with respect to the claimed unit dosage and, as such, the bottled cherry fragrance body oil disclosed by Nicolicchia et al. is (at the least) deemed to contain such a level at some point (e.g., within the initial fragrance prior to incorporating within the edible oil base, or within a certain quantity of the edible oil base). Further, since there are no recited conditions with respect to administering the odorant so as to effect an increase and/or decrease of blood flow to the vagina by the claimed percentage ranges, the inhalation thereof would inherently bring about such an effect (e.g., at some point - perhaps after inhaling for minutes or hours) at least in some

female individuals, especially given the extreme variability of the blood flow effects on different females caused thereby, as instantly disclosed.

Also, again please note that it is legally well established that printed matter - e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, *per se* - i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., *In re Haller*, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 24, 26-33, 36, 39, 41, 42, and 45-48 rejected under 35 U.S.C. 103(a) as being unpatentable over Kunze (US 5,575,992), Hyman (US 4,285,468), Doty (Philadelphia Sensorics, 1983), Vlahakis et al. (US 5,419,879), and/or Nicolicchia (US 5,770,206), in view of the admitted state of the art.

The references are relied upon for the reasons discussed *supra*. As discussed above, each of the cited references teach the inclusion of cherry odorant/aroma/fragrance within their products.

As readily admitted (and demonstrated) by applicants, standardized commercially available odorants/fragrances including cherry are produced by various manufacturers (see, e.g., page 12, lines 1-13) for incorporation into various odorant/fragrance/aroma products.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a result-effective amount (e.g., a non-irritating amount which is pleasant to the olfactory senses) of a commercially available odorant including cherry from a manufacturer such as instantly disclosed as the source of cherry therein so as to beneficially provide a standardized, repeatable, commercially available source of the cherry odorant/fragrance/aroma for their articles of manufacturer or within other art-recognized dispenser type articles such as the wick type odorant dispensers disclosed by Hyman (see, e.g., col 1, lines 17-22).

Also, again please note that it is legally well established that printed matter - e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, *per se* - i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., *In re Haller*, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

Thus, the invention as a whole is clearly *prima facie* obvious over the references, especially in the absence clear and convincing evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.

Christopher R. Tate
Primary Examiner, Group 1651